

facility has been compromised and may present a serious risk to human health, the facility shall provide clinical images and other relevant information, as specified by FDA, for review by the accreditation body or other entity designated by FDA. This additional mammography review will help the agency to determine whether the facility is in compliance with this section and, if not, whether there is a need to notify affected patients, their physicians, or the public that the reliability, clarity, and accuracy of interpretation of mammograms has been compromised.

(2) If FDA determines that the quality of mammography performed by a facility, whether or not certified under § 900.11, was so inconsistent with the quality standards established in this section as to present a significant risk to individual or public health, FDA may require such facility to notify patients who received mammograms at such facility, and their referring physicians, of the deficiencies presenting such risk, the potential harm resulting, appropriate remedial measures, and such other relevant information as FDA may require. Such notification shall occur within a timeframe and in a manner specified by FDA.

[62 FR 55976, Oct. 28, 1997; 62 FR 60614, Nov. 10, 1997, as amended at 63 FR 56558, Oct. 22, 1998; 64 FR 18333, Apr. 14, 1999; 64 FR 32408, June 17, 1999; 65 FR 43690, July 14, 2000]

§ 900.13 Revocation of accreditation and revocation of accreditation body approval.

(a) *FDA action following revocation of accreditation.* If a facility's accreditation is revoked by an accreditation body, the agency may conduct an investigation into the reasons for the revocation. Following such investigation, the agency may determine that the facility's certificate shall no longer be in effect or the agency may take whatever other action or combination of actions will best protect the public health, including the establishment and implementation of a corrective plan of action that will permit the certificate to continue in effect while the facility seeks reaccreditation. A facility whose certificate is no longer in effect because it has lost its accreditation may not practice mammography.

(b) *Withdrawal of FDA approval of an accreditation body.* (1) If FDA withdraws approval of an accreditation body under § 900.6, the certificates of facilities previously accredited by such body shall remain in effect for up to 1 year from the date of the withdrawal of approval, unless FDA determines, in order to protect human health or because the accreditation body fraudulently accredited facilities, that the certificates of some or all of the facilities should be revoked or suspended or that a shorter time period should be established for the certificates to remain in effect.

(2) After 1 year from the date of withdrawal of approval of an accreditation body, or within any shorter period of time established by the agency, the affected facilities must obtain accreditation from another accreditation body, or from another entity designated by FDA.

§ 900.14 Suspension or revocation of certificates.

(a) Except as provided in paragraph (b) of this section, FDA may suspend or revoke a certificate if FDA finds, after providing the owner or operator of the facility with notice and opportunity for an informal hearing in accordance with part 16 of this chapter, that the owner, operator, or any employee of the facility:

(1) Has been guilty of misrepresentation in obtaining the certificate;

(2) Has failed to comply with the standards of § 900.12;

(3) Has failed to comply with reasonable requests of the agency or the accreditation body for records, information, reports, or materials that FDA believes are necessary to determine the continued eligibility of the facility for a certificate or continued compliance with the standards of § 900.12;

(4) Has refused a reasonable request of a duly designated FDA inspector, State inspector, or accreditation body representative for permission to inspect the facility or the operations and pertinent records of the facility;

(5) Has violated or aided and abetted in the violation of any provision of or regulation promulgated pursuant to 42 U.S.C. 263b; or

(6) Has failed to comply with prior sanctions imposed by the agency under 42 U.S.C. 263b(h).

(b) FDA may suspend the certificate of a facility before holding a hearing if FDA makes a finding described in paragraph (a) of this section and also determines that;

(1) The failure to comply with required standards presents a serious risk to human health;

(2) The refusal to permit inspection makes immediate suspension necessary; or

(3) There is reason to believe that the violation or aiding and abetting of the violation was intentional or associated with fraud.

(c) If FDA suspends a certificate in accordance with paragraph (b) of this section:

(1) The agency shall provide the facility with an opportunity for an informal hearing under part 16 of this chapter not later than 60 days from the effective date of this suspension;

(2) The suspension shall remain in effect until the agency determines that:

(i) Allegations of violations or misconduct were not substantiated;

(ii) Violations of required standards have been corrected to the agency's satisfaction; or

(iii) The facility's certificate is revoked in accordance with paragraph (d) of this section;

(d) After providing a hearing in accordance with paragraph (c)(1) of this section, the agency may revoke the facility's certificate if the agency determines that the facility:

(1) Is unwilling or unable to correct violations that were the basis for suspension; or

(2) Has engaged in fraudulent activity to obtain or continue certification.

§ 900.15 Appeals of adverse accreditation or reaccreditation decisions that preclude certification or recertification.

(a) The appeals procedures described in this section are available only for adverse accreditation or reaccreditation decisions that preclude certification or recertification by FDA. Agency decisions to suspend or revoke certificates that are already in effect will be handled in accordance with § 900.14.

(b) Upon learning that a facility has failed to become accredited or reaccredited, FDA will notify the facility that the agency is unable to certify that facility without proof of accreditation.

(c) A facility that has been denied accreditation or reaccreditation is entitled to an appeals process from the accreditation body, in accordance with § 900.7. A facility must avail itself of the accreditation body's appeal process before requesting reconsideration from FDA.

(d) A facility that cannot achieve satisfactory resolution of an adverse accreditation decision through the accreditation body's appeal process is entitled to further appeal in accordance with procedures set forth in this section and in regulations published in 42 CFR part 498.

(1) References to the Health Care Financing Administration (HCFA) in 42 CFR part 498 should be read as the Division of Mammography Quality and Radiation Programs (DMQRP), Center for Devices and Radiological Health, Food and Drug Administration.

(2) References to the Appeals Council of the Social Security Administration in 42 CFR part 498 should be read as references to the Departmental Appeals Board.

(3) In accordance with the procedures set forth in subpart B of 42 CFR part 498, a facility that has been denied accreditation following appeal to the accreditation body may request reconsideration of that adverse decision from DMQRP.

(i) A facility must request reconsideration by DMQRP within 60 days of the accreditation body's adverse appeals decision, at the following address: Food and Drug Administration, Center for Devices and Radiological Health, Division of Mammography Quality and Radiation Programs, Attn: Facility Accreditation Review Committee, 10903 New Hampshire Ave., Bldg. 66, rm. 4521, Silver Spring, MD 20993-0002.

(ii) The request for reconsideration shall include three copies of the following records:

(A) The accreditation body's original denial of accreditation.